Hospital Providers : The Day After FDA Approval

Mitchell DeKoven, MHSA[1]; Brian McCagh, FACHE[2]; and Jeremy Zoch[3]

[1]MEDTAP Institute at UBC Center for Pricing & Reimbursement, Fairfax, Va.;
[2]Washington Cancer Institute, Washington Hospital Center, Washington, D.C.;
[3]University of Maryland Medical Center, Baltimore, Md.

Hospitals have a lot at stake when new biologic drugs and devices hit the market. Cooperation among medical and administrative leaders can help providers avoid some harrowing financial pitfalls – while improving patient satisfaction.

According to the Tufts Center for the Study of Drug Development, it costs, on average, $802 million to develop and win market approval for a new prescription drug in the United States (Tufts 2003). With the enormous cost of bringing a product to commercialization, it is no surprise that for a given product's life cycle, manufacturers emphasize the prelaunch and launch phases — with the postlaunch phase often being disregarded.

The day that a biotechnology company or medical device manufacturer receives U.S. Food and Drug Administration approval of its product is a joyous one. Still, the work to ensure a successful product launch is just beginning. The day after FDA approval is a busy one for healthcare providers — physician offices, hospital outpatient departments, hospital inpatient units, and ambulatory surgery centers.

With a new product available for patients, healthcare providers begin to engage in a series of activities to ensure that patients will have seamless access to the newly approved product. At a time when biologic drug and device reimbursements are declining, and operating expenses are increasing, it is essential that healthcare providers correctly capture overhead costs and charges.

The case studies that follow in this article detail how two large academic urban hospitals responded to the FDA approval of a two new products: a new biologic oncology drug and a new biologic device. The proactive approaches described herein are informative.

Author correspondence:

Mitchell DeKoven, MHSA
Manager
MEDTAP Institute at UBC Center for Pricing & Reimbursement
2700 South Quincy Street, Suite 230
Arlington, VA 22206
(703) 934-9297
mitch.dekoven@unitedbiosource.com

Case study 1

WASHINGTON CANCER INSTITUTE, WASHINGTON HOSPITAL CENTER

The ever-increasing availability of FDA-approved biologic therapies to treat cancer and its associated symptoms has a significant effect on cancer treatment centers. On the surface, it may not appear to be labor intensive, but adding a new biologic cancer drug to a hospital's formulary and connecting all the service "touch points" is a management challenge.

Once the FDA has approved a new biologic drug, the real work within a hospital's infrastructure begins. Hospitals become aware of FDA biologic drug ap-

provals from several sources — most notably, the pharmaceutical representatives who visit hospitals and physician offices, but also through other means, such as articles in trade journals. Physicians and pharmacy directors are at the forefront of these communications.

At the Washington Cancer Institute at the Washington Hospital Center — a major comprehensive, integrated, interdisciplinary cancer program in the nation's capital — FDA product-approval announcements are followed by training for clinical and administrative staff, who are given information about the drug, the criteria for its use, and the potential side effects. These training sessions are a critical step in the dissemination of new drug information.

Mitchell DeKoven, MHSA

Brian McCagh, FACHE

Jeremy Zoch

Acquisition costs, as well as clinical and pharmacoeconomic benefits associated with new biologic cancer therapies — especially the high-cost chemotherapy agents — must be weighed before a decision is made as to whether the new drug will be added to a hospital's pharmacy formulary. This process is started by way of meetings or discussions among key stakeholders, including the pharmacy director, reimbursement director, and purchasing director, just to mention a few.

From there, Washington Cancer Institute administrators and staff take several steps:

- The pharmacy director must ensure that his staff is aware of the new biologic drug and has all of the information needed to assure appropriate utilization.
- The hospital's reimbursement director works with the pharmacy director to ensure that costs are appropriately identified and that charges for the new biologic drug are correctly established.
- The reimbursement director collaborates with the pharmacy director, the information technology staff, and the departments where new biologic therapies will be administered to make any additions and adjustments needed to the hospital's charge master file. This step — designed to ensure accurate coding, charges, billing, and collections — is vital with costly biologic cancer therapies.
- The points of service — where patients receive care or interact with office or billing staff — also must modify their billing sheets to include the new biologic therapy, so as to ensure daily charge capture and reconciliations for optimizing appropriate revenue capture. Appropriate codes (such as J-codes or NDC codes) — often obtained from the coding authorities by the manufacturer before a product launch — are incorporated at this point.
- Next, discussions occur with the purchasing director to establish ordering protocols. In most cases, hospitals are able to purchase new biologic drugs through manufacturers, wholesalers, or specialty pharmacies through group purchasing or discounted purchasing agreements. Being able to buy new oncologic therapies at a fair market price is an important factor if charge codes and reimbursement are to enable the hospital to recover its actual acquisition costs.

Paying close attention to details is critical, because a hospital's costs, charges, coding, billing, and revenue capture are heavily dependent on internal personnel who understand how pharmacy, reimbursement, and purchasing structures interact.

ANALYSIS

All these steps and requirements for achieving effective and efficient cost management and charge reporting have a measurable effect on a hospital's revenue and expense reports. Effective management across this

new-drug continuum is challenging and time consuming. Paying close attention to details is critical, because the hospital's costs, as well as its charges, coding, billing, and revenue capture, are all heavily dependent on various hospital stakeholders who are involved in this process and who understand how the hospital's pharmacy, reimbursement, and purchasing infrastructure works.

The importance of proper charges, coding, medical record documentation, billing and reimbursement, and collections for services provided to cancer patients cannot be stressed enough in today's complicated healthcare environment. Shrinking payment rates often associated with new oncologic therapies only add to the importance of this comprehensive approach.

Case study 2

U.S. EAST COAST ACADEMIC MEDICAL CENTER SURGERY DEPARTMENT[1]

Advancements in biotechnologic therapeutics seem to be matched by advancements in medical devices. Surgeons and other physicians practicing invasive procedures have a wealth of new technologies available to them, almost on an as-needed basis.

The department of surgery at a major East Coast teaching hospital had an opportunity to collaborate with a medical device manufacturer that offered an implant to treat gastrointestinal conditions. New technologies offer the potential for better patient outcomes and overall reduced healthcare costs, as well as increased market exposure and growth for the hospital.

The opportunity is great, but there were several institutional and business risks that needed to be understood before the adoption of this — or any — new technology. In the case of this new device, an initial meeting was convened to discuss considerations relative to minimizing financial risk while maximizing patient satisfaction and outcomes. In attendance at this meeting was a cross-functional group of hospital and physician practice finance experts; operating room, front-line management, and purchasing personnel; the administrative director of clinical operations; and the lead surgeon. The meeting focused on identifying and addressing potential areas of financial exposure and methods of improving patient outcomes.

As many healthcare providers have learned, although a device may be FDA- approved, approval alone does not guarantee reimbursement. Therefore, the surgery department worked aggressively with the device manufacturer to secure resources to assist with financial clearance for facility and professional fees. Often at product launch, the device code is unlisted (i.e., "miscellaneous"), necessitating authorization and payment before completion of the procedure. Such a situation could significantly delay a patient's scheduled procedure or necessitate an out-of-pocket expense. By informing the patient of the effects of reimbursement challenges associated with the device at its launch, the department of surgery was able to improve patient satisfaction and to set realistic expectations about coverage limitations.

Hospitals that are not proactive in their approach to new FDA approvals may find that they will spend a lot of time on the back end, fixing coding, purchasing, and financial errors that could have been avoided with strategic planning and preparation.

In addition to reimbursement difficulties, it is important to consider the financial exposure related to the purchase of the device. Many products are sold in sets or large quantities. In the beginning, the department of surgery recommended — and was able to negotiate — delivery of the product on an as-needed basis, so as to minimize financial risk and to manage its inventory. This is not unlike the acquisition of capital equipment, which often is leased for the first 5 to 10 cases following a product launch so the hospital can accumulate reimbursement data and coverage experience.

Because patients' expectations have a direct influence on their satisfaction level, it is important to provide concise information about the expected outcomes and the details of the process. Consequently, the de-

[1] The author has requested that the medical center in question remain masked. BIOTECHNOLOGY HEALTHCARE has verified the accuracy of this report.

partment of surgery, working with the device manufacturer, developed patient-education brochures that outlined reasonable clinical, financial, and operational expectations. The department let patients know up front that the procedure would be scheduled 6 to 8 weeks after identification of the need for the procedure — which allowed for the time needed to address payment authorization for the new technology.

ANALYSIS

Device growth will continue to increase over the next several years, making it essential to identify a thorough and fair process for assessing and implementing new technologies. The physician will continue to drive many choices for new technologies, but success depends on an organized team capable of addressing each component so that new technologies are adopted smoothly.

CONCLUSION

The steps described in these case studies are intensive and time consuming, and they entail cooperation by departments and staff that do not normally interact on a day-to-day basis. In these cases, it is essential that turf becomes a non-issue, as the ultimate goal of the organization and the recuperation of costs must be brought to the forefront. Every team member, from physicians to back-office clerical staff, needs to understand each other's role in the process, as well as the downstream effect (for instance, how a coding error might affect the accounts receivable cycle), even if the specific care site's cost center is not the one that would be affected by payer denials.

Although often a lack of communication or leadership prevents this sort of team approach, it is certainly recommended to ensure that the proper steps are implemented following FDA approval of a new biological or device.

It is also important to measure the results of the team's effort. Financial goals might include a specific collection rate by the billing office, a certain number of days in accounts receivable, or a budget-impact analysis of the drug or device in the physician practice or hospital. If these goals are not met, hospitals at least will have targets (such as renegotiating contracts, redesigning preregistration procedures, or seeking alternative funding sources for the uninsured population) to pursue to improve the situation.

Hospitals that are not proactive in their approach to new FDA drug, device, and diagnostic approvals may ultimately find that they will spend more time on the "back end," correcting coding, purchasing, and financial errors that could have been averted with strategic planning and preparation. To assist hospitals with their back-end efforts, many biotechnology companies and medical device manufacturers are starting to emphasize the postlaunch phase of their products' life cycles so that payment becomes as seamless as possible.

As described in these case studies, health care providers look to biotech companies and device manufacturers for payment-support services. Examples of such strategies and pull-through programs might include:

- Communication tools for providers and patients, including coding guides, reimbursement brochures, and support materials for the claims process
- Reimbursement case management for support and problem solving, including claims-denial research and assistance for the uninsured population
- Manufacturers' deployment of payer access teams to educate third-party payers about the clinical and/or economic benefits of a product
- Strategies for prior authorization
- Field-force-payment and economic-support tools and training, which help to communicate the product's value to various stakeholders

As the payment and health insurance landscape in the United States continues to change, the day after FDA approval becomes ever more critical when it comes to containing costs without sacrificing patient care. BH

REFERENCE

Tufts Center for the Study of Drug Development. *Impact Report*. 2002 Sept./Oct.;4(5). Available online: «http://csdd.tufts.edu/InfoServices/ImpactReportPDFs/ImpRptOct2002.pdf». Accessed May 24, 2005.
[Editor's note: the $802 million figure cited since has been updated by the source to include postmarketing costs, boosting the new-drug development figure to $897 million. See: Tufts Center for the Study of Drug Development. Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is $897 Million. News Release. Boston: Tufts. May 13, 2003. Available online: «http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29». Accessed May 25, 2005.